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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/929,782	08/13/2001	Robert O. Ralston	154.206	1144

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CHIRON CORPORATION
Intellectual Property
P.O. Box 8097
Emeryville, CA 94662-8097

EXAMINER	
HILL, MYRON G	
ART UNIT	PAPER NUMBER
1648	3

DATE MAILED: 12/11/2001

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Applicati n No. 09/929,782	Applicant(s) RALSTON ET AL.	
	Examiner Myron G. Hill	Art Unit 1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *20- 23 and 44- 79* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *20- 23 and 44- 79* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

The following claims are being considered in this action: 20- 23 and 44- 79. Claims 1- 19 and 24- 43 are cancelled.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 20, 44, 56, and claims that depend on them are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The term "specific" in the phase "antibody specific for said hepatitis c virus (HCV) glycoprotein" in claims 20, 44, 56, and claims that depend on them is a relative term which renders the claim indefinite. The term is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. It is not explained how this antibody reacts differently than an antibody to an E1 and/ or E2 glycoprotein of HCV that has more than 10% total N-linked carbohydrate is sialic acid. It is not clear if this antibody recognizes only this protein or if it binds the protein well (affinity). It is not clear what the specificity to other proteins with mannose terminated glycosylation.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 20- 23, and 44- 79 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for antigen production, does not reasonably provide enablement for specific antibodies. Since it is not clear how specific is defined, one cannot produce "specific" antibodies without any understanding of what "specificity" is required. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims. While no working examples are required, the specification does not teach specific antibodies. There is no indication of how specific the binding is for the stated HCV glycoprotein is or how it differs from antibodies produced from other antigens.

Claims 20- 23, and 44- 79 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for concept of using an antigen to make an antibody, does not reasonably provide enablement for making an antibody "specific for" the stated antigen. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims. The claims are drawn to antibodies that would be "specific" for glycoprotein(s) expressed from the E1 and/ or E2 regions of hepatitis C virus (HCV) having mannose terminated glycosylation and having less than

about 10% of the N-linked carbohydrate is sialic acid. While making polyclonal antibodies is well know in the art, it is also known that different animals can have different responses to the same antigen preparation. This includes dominance of the epitopes seen and the conformation of the epitope recognized. The specification gives no guidance on how the claimed antibody will be "specific" or react differently than one that is made from an antigen prepared in another way. There is no guidance in the specification that states that the claimed antibody would bind to stated antigen and not to other mannose terminated glycoproteins. Also, there is no statement as to the affinity of binding or the sites recognized by the antibody. Even though working examples are not required, there are no examples of how the antibody would be expected to be "specific" and how this differs from other antibodies. Screening of polyclonal antibodies is routine laboratory work; however, in not having defined criteria for the specificity of the antibody, it may take undue experimentation to determine if an antibody has the "specificity" claimed or if it is not specific enough.

Claims 20- 23, and 44- 79 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The disclosure lacks expected results of claimed antibodies and examples that show the specificity of the claimed antibody.

Papers relating to this claim may be faxed to Technology Sector 1 by facsimile transmission. Papers should be faxed to Crystal Mall1, ART Unit 1648, using fax number 703- 308-4242. All Sector 1 fax machines are able to receive fax transmissions 24 hours/ day, 7 days/ week. Please note the faxing of such papers must conform with the Notice published in the Official Gazette, 1096 OG 30 (November 15, 1989).

Any inquiry concerning this communication should be directed to Myron Hill (703) 308-4521. The Examiner can normally be reached Monday- Friday from 9:00 AM- 6:00 PM. If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, James Housel, can be reached at (703) 308- 4027.

Any enquiry of a general nature or relating to the status of this application should be directed to the receptionist whose telephone number is (703) 308-0196.

Myron Hill
Patent Examiner
Group Art Unit 1648
7 December 2001

MARY E. MOSHER
PRIMARY EXAMINER
GROUP 1800
1600